

EP 0 169 319 B1



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number:

0 169 319 B1

(12)

EUROPEAN PATENT SPECIFICATION

(15) Date of publication of patent specification: 04.08.93 (51) Int. Cl. 5: A61K 9/36

(21) Application number: 85105508.7

(22) Date of filing: 06.05.85

(50) Maltodextrin coating.

(52) Priority: 24.07.84 US 633954

(43) Date of publication of application:
29.01.86 Bulletin 86/05

(45) Publication of the grant of the patent:
04.08.93 Bulletin 93/31

(60) Designated Contracting States:
BE CH DE FR GB IT LI NL

(61) References cited:
EP-A- 0 063 014 DE-A- 2 522 483
FR-A- 2 506 570 GB-A- 2 065 691
US-A- 3 395 213 US-A- 3 917 874
US-A- 3 981 984

CHEMICAL ABSTRACTS, vol. 85, no. 14, 4th October 1976, page 320, abstract no. 99119K, Columbus, Ohio, US; H.H. VOELKER:
"Maltodextrin: raw material for dragee manufacture. Comparison of some properties of gum arabic and maltodextrin", & SUES-SWAREN 1976, 20(8), 207-12, 214

CHEMICAL ABSTRACTS, vol. 94, no. 15, 13th April 1981, page 550, abstract no. 119740X, Columbus, Ohio, US; A. VOILLEY et al.:
"Retention of aroma during freeze- and air-

drying", & FOOD PROCESS ENG., [Proc. Int. Congr.] 2nd 1979 (Pub. 1980), 371-84

(73) Proprietor: BERWIND PHARMACEUTICAL SERVICES, INC.
Moyer Boulevard
West Point, PA 19486(US)

(72) Inventor: Porter, Stuart C.
675 Brighton Drive
Hatfield Pennsylvania 19440(US)
Inventor: Woznicki, Edward J.
201 Elliot Drive
Douglassville Pennsylvania 19518(US)

(74) Representative: von Füner, Alexander, Dr. et al
Patentanwälte v. Füner, Ebbinghaus, Finck
Mariahilfplatz 2 & 3 Postfach 95 01 60
W-8000 München 95 (DE)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

This invention relates to the field of coating pharmaceutical, confectionery, and food tablets and the like including medicinal tablets, vitamin tablets, aspirin tablets, capsules, gum balls, and candy pieces.

5 Film coating of pharmaceutical, confectionery and food tablets with film coating polymers, such as hydroxypropyl methyl cellulose (HPMC), is known. U.S. patent no. 3,981,984 discloses such coatings and is incorporated herein by reference together with the patents cited therein.

While HPMC and the other film coating polymers known in the art provide effective coatings, they are rather expensive, and have a somewhat disagreeable slimy taste.

10 In CHEMICAL ABSTRACTS, vol. 85, no. 14, 4th October 1976, page 320, abstract no. 99119k, Columbus, Ohio, USA; H.H. VOELKER there is reported about tests comparing the suitability of Snowflake 01908, Snowflake 01911, and Snowflake 01913 maltodextrins and gum arabic (9000-01-5) as coatings for dragee manufacture. These tests showed that the adhesive properties of maltodextrin are comparable to those of gum arabic. The maltodextrin-coated sugar centers were harder than those coated with gum arabic,

15 possibly because of the greater uptake of water (15%) by gum arabic than by maltodextrin (5%). The increase in wt. of the dragee was also less with maltodextrin. The maltodextrin dragees were superior with regard to taste. Thus, Snowflake 01911 gave better results as a binder and dry dust than gum arabic, and Snowflake 01908 also gave excellent results.

20 The DE-A-2 522 483 refers to a process for preparing coated tablets, characterized by spray-coating an aqueous solution of a cellulose derivative, said aqueous solution containing polyethylene glycol, with a simultaneous supply of air heated up to 60 - 120° C, preferably to 75 - 80° C.

25 GB-A-2 065 691 refers to a dry powder edible film coating composition for use in pharmaceuticals, confectionery and food which comprises a solvent-free dry mixture including powdered particles of a film forming non-toxic polymer, powdered edible pigment particles, an edible plasticizer and, optionally, a surfactant. The composition can be prepared by mixing a powder of the film forming polymer and powdered pigment particles in a blender to form a polymer-pigment mix, and then adding and blending the plasticizer, optionally pre-mixed with a surfactant. Before use, the powder composition is dispersed in an aqueous or non-aqueous solvent to form a liquid coating composition; dispersion is achieved quite quickly without agglomeration of the powder particles. The polymer may be zein, a cellulose derivative, or a vinyl polymer.

30 EP-A-0 063 014 refers to a method of coating a solid material with a polymer, characterized in that a material is coated with a powdered film-forming polymer and with a liquid plasticizer having an affinity for the polymer.

Finally, US-A-3 395 213 refers to a novel dragee product as well as the process of the manufacturing of the same, whereby the dragee comprises an inner pill center, i.e., a drug, gum or confectionary core, and an outer encapsulating layer comprising a dried admixture of a liquid carrier and from about 1-10 wt.-percent of polyethylene glycol, 40-50 wt.-percent of sugar and 10-20 wt.-percent of solid fillers.

The dragee is produced by the steps of applying to the pill centers a suspension as just described, agitating the pill centers to distribute the suspension uniformly onto the surface of the same and then drying the coated centers by contacting the same with heated gas.

40 It is an object of this invention to provide a coated pharmaceuticals confectionery and food tablet which is effectively coated with a film coating other than the known film coating polymers such as HPMC having superior properties.

It is another object to provide such a coating composition is less expensive and which eliminates disagreeable tastes such as a slimy taste.

45 The objects of the invention are accomplished by providing a coating composition of maltodextrin modified so that it is non-brittle and non-cracking and forms an effective coating.

In detail, the improvement according to the invention consists in a pharmaceutical, confectionery or food tablet and the like coated on all of its exterior surfaces with maltodextrin, and which coated tablet does not have the characteristic taste of the tablet ingredients and does not have a slimy taste.

50 Object of the invention is so a dry powder edible film coating composition for use in pharmaceutical, confectionery and food tablets, comprising a dry mixture obtained by dry blending ingredients, including powdered particles of film forming non-toxic edible maltodextrin, a plasticizer and a detackifier, the plasticizer being 3.5% to 15% of the weight of the coating composition, the detackifier being 2% to 20% by weight of the coating composition.

55 A tablet is uniformly coated with 0.5 to 5 parts by weight of maltodextrin composition per 100 parts by weight of the tablet.

The maltodextrin contains an effective amount of plasticizer. This plasticizer may be present in an amount of 3.5 to 15% by weight of the coating composition. Preferred as plasticizer is polyethylene glycol

400. Furthermore, preferred is hydrogenated glucose syrup, polyethylene glycol 3350, polyethylene glycol 8000, triacetin, acetyltriethyl citrate, or glycerine or a combination thereof.

Preferred detackifiers are modified derivatized starch, crystal gum, polyethylene glycol 3350, or polyethylene glycol 8000.

5 The coating composition may contain, too, an effective amount of a secondary film former, preferably in a range of 3 to 15% by weight of the coating composition. A secondary film former is preferred propylene glycol alginate.

The coating composition may contain an effective amount of color ingredients, whereby there are preferred titanium dioxide, FD&C lakes, or D&C lakes.

10 The color ingredients may be contained in an amount of 0 to 20% of the weight of the solids content of the tablet coating.

Furthermore preferred as color ingredients being FDA approved soluble dyes and titanium dioxide, whereby these dyes are especially contained in a range of 0 to 2% by weight of the coating composition, and the titanium dioxide in a range of 0 to 10% by weight of the coating.

15 Object of the invention is also a method for preparing the pharmaceutical, confectionery or food tablet and the like which does not have the characteristic taste of the tablet ingredients and does not have a slimy taste, according to one of the claims 1-17, comprising aqueous spray-coating composition containing maltodextrin onto all exterior surfaces of a tablet to form a coating, the amount of maltodextrin being effective to protect the tablet ingredients from moisture and to mask the characteristic taste of the 20 ingredients and to avoid esophageal discomfort and to provide for the tablet disintegrating in the stomach not materially slower than an uncoated tablet.

It is preferred to spray the aqueous coating composition onto uncoated tablets in a slowly rotating baffled pan in a chamber equipped to measure and control both inlet and outlet air flow rates and temperatures, the inlet and outlet air flow rates and temperatures being sufficient to insure rapid evaporation 25 of the water and to provide an evenly-applied coating of maltodextrin onto the uncoated tablets without causing their decomposition and/or physical disintegration.

It is preferred that the composition used contain 2 to 15% by weight of maltodextrin in water, especially 4 to 8% by weight.

In case of using a secondary film former, it is preferred to use propylene glycol alginate as mentioned 30 above and to use the secondary film former in a range of 3 to 15% by weight of the coating composition.

The amounts and representatives of preferred color ingredients are mentioned above.

As a tablet to be coated it is preferred to use aspirin.

A further object of the invention is a dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture obtained by dry blending ingredients, 35 including powdered particles of film forming non-toxic edible maltodextrin, above mentioned amount of a plasticizer and a detackifier.

The amounts of components and special ingredients are mentioned above with the tablet as well as the method for preparing.

40 The maltodextrin tablet composition of the invention shows enhanced color stability with water soluble dyes, as good as previous tablet coatings made with film forming polymers such as HPMC. Moreover, the maltodextrin tablet coating demonstrated a much greater color intensity than a HPMC system.

Normally, when pigment particles are added to a coating dispersion, the pigment particles weaken the film strength of the polymer film former such as HPMC. Surprisingly, adding pigment particles to the maltodextrin coating dispersion enhances the film strength of the maltodextrin and reduces cracking. This is 45 totally unexpected.

Tablet film coating experts have not recognized maltodextrin as a film coating because of its brittleness and tendency to crack.

As the art of tablet coating moved from sugar to film, the tablet coating lost some of its elegance and gloss. Film coated tablets do not have the high gloss of sugar coated tablets. However, with maltodextrin 50 coated tablets, a high gloss is obtained, higher gloss than film coated tablets and matching that of sugar coated tablets.

The maltodextrin coating also shows high tint strength.

Color pigments are known to give superior color stability in polymer film formers such as HPMC, while soluble dyes give brighter color, but are less stable in HPMC. However, maltodextrin coatings with soluble 55 dyes have brighter color and more stability than HPMC coatings with soluble dyes. This is unexpected, that maltodextrin soluble dye coatings are more brilliant and more stable.

The weight gain of the tablet caused by the addition of the maltodextrin coating is 0.5 to 2.0% on aspirin with 1% being preferred, about 3% on confection tablets, and about 3% on pharmaceutical tablets.

The viscosity of the maltodextrin coating suspension is very low, so although a coating dispersion of 15 parts solids in 85 parts water is preferred, a mixture of 25 to 30 parts solids to 70 to 75 parts water at room temperature is workable for spray coating, and solids loading of 50-60% is obtainable. If you heat the coating suspension, more solids may be added to the maltodextrin coating suspension, which is just the opposite with a HPMC coating suspension. An advantage of using hot maltodextrin coating suspensions is that the air temperature in the spray coating process may be kept below the air temperature required in spray coating with a HPMC coating suspension. This saves energy, and also makes it easier to coat gumballs which are sensitive to heat. Coating gumballs with HPMC coating suspensions may take 4 to 6 hours, while coating gumballs with maltodextrin coating suspensions may take 1 to 1.5 hours.

This invention is concerned with coating tablets, which are defined herein as pharmaceutical, confectionery and food tablets including medicinal tablets, vitamin tablets, aspirin tablets, capsules, chewing gum balls and pieces of candy.

In accordance with the method invention, a coating mixture is made of maltodextrin which acts as a film former in the coating on the tablets, a plasticizer for making the coating non-brittle and non-cracking,¹ and a detackifier for making the coating non-tacky. Other ingredients may include a secondary film former to give a high gloss and strength to the coating on the tablet, and color ingredients to give a desired color to the tablet coating.

The maltodextrin may be Maltrin maltodextrins made by Grain Processing Corp., Muscatine, Iowa, or Amaizo Lo-Dex maltodextrins made by American Maize-Products Company, Hammond, Indiana. By definition, maltodextrins (hydrolyzed cereal solids) are starch hydrolysates produced by converting pure refined corn starch into nutritive saccharides through the use of acids or specific enzymes. The carbohydrate composition is arranged to yield a DE (dextrose equivalent) of less than 20.

Maltodextrin by itself forms a film coating which is brittle and cracks, so that a tablet coated with maltodextrin is not protected from moisture which may penetrate the coating through the cracks. To prevent brittleness and cracking, a plasticizer is mixed in with the maltodextrin. Suitable plasticizers include hydrogenated glucose syrup (Lycasin), polyethylene glycol 400, 3350, and 8000, triacetin (triethylcitrate), acetyltriethyl citrate, propylene glycol and glycerine. The plasticizers are used in a range of 3.5 to 15% by weight of the coating mixture, alone or in some combination, with 5 to 10% being preferred. Certain plasticizers cause considerable tackiness during tablet coating, but in combination with another plasticizer used as a detackifier, the tack is considerably reduced or eliminated.

Suitable detackifiers include polyethylene glycol 3350 and 8000, crystal gum (tapioca dextrin) and a modified derivatized starch, starch octenyl succinate, except that it is made from standard corn starch instead of a waxy starch. The range of detackifiers is 2 to 20% by weight of the coating mixture with 10% being preferred.

The coating composition may include a secondary film former to impart gloss and strength to the maltodextrin. Suitable secondary film formers are sodium alginate and propylene glycol alginate and they are used in a range of 3 to 15% by weight of the coating mixture, with 10% being preferred. The propylene glycol alginate may be a low viscosity Kelcoloid STM, and the sodium alginate may be a higher viscosity Kelcoloid LVF. The Kelcoloid LVFTM may be about 5% by weight of the dry coating mixture without making it too viscous. The Kelcoloid STM may be about 10% by weight of the dry coating mixture before the mixture becomes too viscous.

The coating composition may or may not be pigmented. The addition of pigment particles adds strength to the maltodextrin film coatings. However, as the percentage of pigment particles increases, the gloss of the coated tablet decreases. Pigments are used in the range of 0 to 20% by weight of the mixture, and may include any U.S. Food and Drug Administration (FDA) approved FD & C aluminum lakes, D & C lakes, and titanium dioxide. A list of such pigments appears in Signorino U. S. Patent 3,981,984, which is incorporated herein by reference.

The coating may be colored by using FDA approved soluble dyes and titanium dioxide. The range of dye used is 0 to 2% by weight of the coating mixture, and the range of titanium dioxide is 0 to 10% by weight of the coating mixture.

All units and percentages used herein are by weight.
The following examples illustrate the invention as applied to film coating of pharmaceutical, food and confectionery, with gum balls being chosen as a specific example because of its sensitivity to high temperatures.

Example 1

A coating composition is made according to the following formula by mixing the ingredients in a blender until all the ingredients are evenly dispersed throughout the mixture.

5

10

69.5 g	maltodextrin (Maltrin M150)
3.0 g	polyethylene glycol 400
5.0 g	polyethylene glycol 3350
3.0 g	glycerine
10.0 g	propylene glycol alginate
8.0 g	titanium dioxide
1.5 g	FD&C yellow #5 aluminum lake
100.0 g	

15

The maltodextrin is the film former, the polyethylene glycol 400 and the glycerine are the plasticizers, the polyethylene glycol 3350 is the detackifier, the propylene glycol alginate is the secondary film former, the titanium dioxide is an opacifier, and the FD&C yellow #5 gives the coating a yellow color.

The maltodextrin is non-toxic, edible and is in powdered form and is mixed in with the other ingredients in the formula.

A spraying suspension is made by suspending 15 parts by weight of the coating composition in 85 parts by weight of water with suitable agitation to disperse the mixture in the suspension.

3.8 kg of 1.905 cm (3/4 inch) gum balls are placed in a 60.96 cm (24 inch) conventional pan which is rotated at 22 rpm. The spraying suspension is sprayed onto the gum balls by a 460 Binks air gun, with a 25 7016 Masterflex peristaltic pump, at 2.72 Atmospheres (40 psi) atomizing pressure delivered at a rate of 15 grams per minute. The drying air is at 45°C, and the coating suspension is heated to 70°C, application time is 15 minutes and 115 grams total of film is applied to the gum balls.

The maltodextrin 150 is used as a film former. The maltodextrin without other ingredients produces a film coating on a tablet which is brittle and cracks. To overcome this brittleness and cracking, the polyethylene glycol 400 and the glycerine are provided as plasticizers. However, this makes the coating sticky so to overcome this stickiness, polyethylene glycol 3350 is provided as a detackifier. The propylene glycol alginate acts as a secondary film former to give the coating a desired gloss. The titanium dioxide and FD&C yellow No. 5 aluminum lake are provided as color ingredients, with the titanium dioxide acting as an opacifier and the yellow lake providing a yellow color to the coating.

35

Example 2

A coating composition is made up as in Example 1 but having the following formula with 1.0 g of FD&C yellow dye being substituted for the 1.0 g of FD&C yellow No. 5 aluminum lake.

40

45

69.5 g	maltodextrin
3.0 g	polyethylene glycol 400
5.0 g	polyethylene glycol 3350
3.0 g	glycerine
10.0 g	propylene glycol alginate
8.5 g	titanium dioxide
1.0 g	FD&C yellow No. 5 dye
100.0 g	

50

The ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls are spray coated as in Example 1.

55

Example 3

A coating composition is made up as in Example 1 but having the following formula.

5	70.0 g	maltodextrin
	3.5 g	polyethylene glycol 400
	3.5 g	polyethylene glycol 3350
	3.0 g	sodium alginate
10	10.0 g	titanium dioxide
	10.0 g	FD&C yellow No. 6 aluminum lake
	100.0 g	

The ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls
15 are spray coated as in Example 1.

Example 4

A coating composition is made up as in Example 1 but having the following formula.

20	65.0 g	maltodextrin
	10.0 g	polyethylene glycol 400
	5.0 g	polyethylene glycol 3350
25	15.0 g	propylene glycol alginate
	5.0 g	titanium dioxide
	100.0 g	

The ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls
30 are spray coated as in Example 1.

Example 5

A coating composition is made up as in Example 1 but having the following formula.

35	69.0 g	maltodextrin
	3.5 g	polyethylene glycol 400
	3.5 g	polyethylene glycol 3350
40	4.0 g	sodium alginate
	10.0 g	titanium dioxide
	10.0 g	FD&C No. 3 aluminum lake
	100.0 g	

45 The ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls
are spray coated as in Example 1.

50

55

EP 0 169 319 B1

Example 6

A coating composition is made up as in Example 1 but having the following formula.

5

60.0 g	maltodextrin
15.0 g	polyethylene glycol 400
5.0 g	polyethylene glycol 3350
5.0 g	sodium alginate
15.0 g	titanium dioxide
100.0 g	

10

The coating ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls are spray coated as in Example 1.

15

Example 7

A coating composition is made up as in Example 1 but having the following formula.

20

75.0 g	maltodextrin
10.0 g	polyethylene glycol 400
5.0 g	polyethylene glycol 3350
10.0 g	propylene glycol alginate
100.0 g	

25

The ingredients are mixed and a coating suspension is prepared as in Example 1, and the gum balls are spray coated as in Example 1.

Other formulations of coating composition which are made into a coating suspension or solution, and which are spray coated onto tablets, are as follows:

Example 8

35

73.0 g	maltodextrin
5.0 g	hydrogenated glucose syrup
5.0 g	polyethylene glycol 400
10.0 g	propylene glycol alginate
6.0 g	titanium dioxide
1.0 g	FD&C yellow #6 dye
100.0 g	

40

Example 9

50

68.0 g	maltodextrin
10.0 g	hydrogenated glucose syrup
5.0 g	polyethylene glycol 400
10.0 g	propylene glycol alginate
6.0 g	titanium dioxide
1.0 g	FD&C yellow #6 dye
100.0 g	

55

Example 10

5	68.0 g 5.0 g 10.0 g 10.0 g 6.0 g 1.0 g <hr/> 100.0 g	maltodextrin hydrogenated glucose syrup polyethylene glycol 400 propylene glycol alginate titanium dioxide FD&C yellow #6 dye
10		

Example 11

15

20

75.0 g 13.0 g 2.0 g 10.0 g <hr/> 100.0 g	maltodextrin polyethylene glycol 400 polyethylene glycol 3350 sodium alginate
--	--

25 Example 12

30

35

69.5 g 3.0 g 5.0 g 3.0 g 10.0 g 7.5 g 2.0 g <hr/> 100.0 g	maltodextrin polyethylene glycol 400 polyethylene glycol 3350 glycerine propylene glycol alginate titanium dioxide FD&C yellow #5 dye
--	---

Conventional film forming polymeric spray coating suspensions, like those made with HPMC, thicken and gel at high temperatures. In contrast to this, it has been found that the herein described maltodextrin 40 coating suspensions become less viscous at high temperatures, which is an advantage in spray coating suspensions having a high solids content. Also, since the maltodextrin coating suspensions can be heated they can be sprayed on heat sensitive materials, like gum balls, without using excessively hot drying air that would harm the gum balls. In other words, the heated maltodextrin coating suspension does not harm the gum balls, whereas the heated drying air would. For example, the maltodextrin coating suspensions have 45 been successfully sprayed onto tablets at temperatures of 80°C with the drying air at 30°C. Also, the maltodextrin coating suspensions have been successfully sprayed onto tablets at room temperature with the drying air at 80°C. Tablets may be successfully sprayed by the maltodextrin coating suspensions at all temperatures within those ranges.

Maltodextrin coating suspensions are used to coat aspirin tablets which are easily-swallowed, powder-free, gastric disintegrable, thinly-coated, and which do not have the characteristic aspirin taste, do not produce the esophageal discomfort of an uncoated aspirin tablet, and which disintegrate in the stomach not much slower than an uncoated aspirin tablet. The method of coating aspirin tablets comprises aqueous spray-coating maltodextrin onto all exterior surfaces of the aspirin tablets, with the maltodextrin being 0.5 to 2.0 parts by weight per 100 parts by weight of the uncoated aspirin tablet.

In one embodiment of the method, an aqueous coating solution is made of 2% to 15% by weight of a 55 coating mixture of the maltodextrin 60-70%, plasticizer about 10%, detackifier 10-20%, and secondary film former about 10%, with 85-98% water, and thin coating solution is sprayed onto uncoated aspirin tablets in a conventional coating pan in a chamber with the inlet and outlet air rates and temperature being effective

EP 0 169 319 B1

to rapidly evaporate the water and to apply a thin coating of maltodextrin onto the tablets without causing them to decompose or disintegrate.

The coated aspirin tablet comprises an easily-swallowed, powder-free and gastric-disintegrable aspirin tablet thinly coated on all exterior surfaces with maltodextrin, with the coating being thin enough not to change significantly the rate of disintegration in the stomach. The coating masks the characteristic taste of aspirin, and smooths the ingestion of the aspirin tablet through the esophagus. In a preferred embodiment the aspirin tablet is uniformly covered with a coating of maltodextrin 60-70%, plasticizer about 10%, detackifier 10-20%, and secondary film former about 10%.

The following examples illustrate the coated aspirin embodiment of the invention.

10

Example 13

A dry coating composition is made up as in Example 1 but having the following formula.

15

70 g	maltodextrin
10 g	polyethylene glycol 400
10 g	modified derivatized starch
10 g	propylene glycol alginate
100 g	

20

A coating solution is prepared by suspending 15 parts by weight of the mixture in 85 parts of water by agitation, and aspirin tablets are spray coated as in Example 1.

25 Example 14

The method of Example 13, except the coating solution is prepared by suspending 2 parts by weight of the mixture into 98 parts of water.

30 Example 15

A coating composition is made as in Example 1 having the following formula.

35

60.0 g	maltodextrin
10.0 g	polyethylene glycol 400
20.0 g	modified derivatized starch
10.0 g	propylene glycol alginate
100.0 g	

40

A coating solution is made as in Example 13 and aspirin tablets are spray coated as in Example 13.

Example 16

45

A coating composition is made as in Example 1 having the following formula.

50

70.0 g	maltodextrin
10.0 g	polyethylene glycol 400
10.0 g	crystal gum (tapioca dextrin)
10.0 g	propylene glycol alginate
100.0 g	

A coating solution is made as in Example 13 and aspirin tablets are spray coated as in Example 13.

55

Example 17

A coating composition is made as in Example 1 having the following formula.

5	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">60.0 g</td><td style="padding: 2px;">maltodextrin</td></tr> <tr> <td style="padding: 2px;">10.0 g</td><td style="padding: 2px;">propylene glycol 400</td></tr> <tr> <td style="padding: 2px;">20.0 g</td><td style="padding: 2px;">crystal gum (tapioca dextrin)</td></tr> <tr> <td style="padding: 2px;">10.0 g</td><td style="padding: 2px;">propylene glycol alginate</td></tr> <tr> <td style="padding: 2px; border-top: 1px solid black;">100.0 g</td><td style="padding: 2px; border-top: 1px solid black;"></td></tr> </table>	60.0 g	maltodextrin	10.0 g	propylene glycol 400	20.0 g	crystal gum (tapioca dextrin)	10.0 g	propylene glycol alginate	100.0 g	
60.0 g	maltodextrin										
10.0 g	propylene glycol 400										
20.0 g	crystal gum (tapioca dextrin)										
10.0 g	propylene glycol alginate										
100.0 g											
10											

A coating solution is made as in Example 15 and aspirin tablets are spray coated as in Example 15.

Claims

- 15 1. A dry powder edible film coating composition for use in pharmaceutical, confectionery and food tablets, comprising a dry mixture obtained by dry blending ingredients, including powdered particles of film forming non-toxic edible maltodextrin, a plasticizer and a detackifier, the plasticizer being 3.5% to 15% of the weight of the coating composition, the detackifier being 2% to 20% by weight of the coating composition.
- 20 2. The dry powder edible film coating composition according to claim 1, wherein the plasticizer is polyethylene glycol 400, hydrogenated glucose syrup, polyethylene glycol 3350, polyethylene glycol 8000, triacetin, acetyl triethyl citrate, glycerine, or a combination thereof.
- 25 3. The dry powder edible film coating composition according to claims 1 or 2, said detackifier being modified derivatized starch, crystal gum, polyethylene glycol 3350, or polyethylene glycol 8000.
- 30 4. The dry powder edible film coating composition of one of the claims 1 to 3, including a secondary film former in a range of 3% to 15% by weight of the coating composition.
5. The dry powder edible film coating composition of claim 4, the secondary film former being propylene glycol alginate.
- 35 6. The dry powder edible film coating composition of one of the claims 1 to 5, including color ingredients in the range of 0% to 20% of the weight of the solids content of the coating composition.
7. The dry powder edible film coating composition of claim 6, wherein said color ingredients are titanium dioxide, FD&C lakes, or D&C lakes.
- 40 8. The dry powder edible film coating composition of claim 7, the titanium dioxide being in a range of 0% to 10% by weight of the coating.
9. The dry powder edible film coating composition of claim 6, wherein said color ingredients are soluble dyes in a range of 0% to 2% by weight of the coating.
- 45 10. A pharmaceutical, confectionery or food tablet coated on all of its exterior surfaces with a coating composition according to one of the preceding claims.
- 50 11. A method for preparing the pharmaceutical, confectionery or food tablet according to claim 10, comprising aqueous spray-coating the coating composition according to any one of Claims 1 to 8 onto all exterior surfaces of a tablet to form a coating.
- 55 12. A method according to claim 11, which comprises spraying the aqueous coating composition onto uncoated tablets in a slowly rotating baffled pan in a chamber equipped to measure and control both inlet and outlet air flow rates and temperatures, the inlet and outlet air flow rates and temperatures being sufficient to ensure rapid evaporation of the water and to provide an evenly-applied coating onto the uncoated tablets without causing their decomposition and/or physical disintegration.

Patentansprüche

1. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers für die Herstellung von Tabletten für pharmazeutische Zwecke, Nahrungsmittelzwecke sowie für Konditorwaren, das ein Trockengemisch umfaßt, erhalten durch Trockenmischung der einzelnen Komponenten einschließlich pulverförmiger Teilchen von filmbildendem nichttoxischem eßbarem Maltodextrin sowie eines Weichmachers und eines Antiklebemittels, wobei der Weichmacher 3,5 bis 15 Gew.-% und das Antiklebemittel 2 bis 20 Gew.-% des Befilmgemisches ausmachen.
- 10 2. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 1, worin der Weichmacher Polyethylen glycol 400, hydrierter Glucosesirup, Polyethylen glycol 3350, Polyethylen glycol 8000, Triacetin, Acetyltriethylcitrat, Glycerin oder ein Gemisch davon ist.
- 15 3. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 1 oder 2, worin das Antiklebemittel modifizierte derivierte Stärke, kristallines Pflanzengummi, Polyethylen glycol 3350 oder Polyethylen glycol 8000 ist.
4. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach einem der Ansprüche 1 bis 3, das außerdem noch 3 bis 15 Gew.-%, bezogen auf das Befilmgemisch, eines zweiten Filmbildners enthält.
- 20 5. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 4, worin der zweite Filmbildner Propylenglycolalginat ist.
6. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach einem der Ansprüche 1 bis 5, das außerdem noch 0 bis 20 Gew.-%, bezogen auf den Feststoffgehalt des Befilmgemisches, an Farbstoffen enthält.
- 25 7. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 6, worin die Farbstoffe Titandioxid, FD- und C-Lacke oder D- und C-Lacke sind.
8. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 7, bei dem das Titandioxid in einer Menge von 0 bis 10 Gew.-% der Beschichtung vorliegt.
- 30 9. Eßbares Befilmgemisch auf der Basis eines Trockenpulvers nach Anspruch 6, worin die Farbstoffe lösliche Farbstoffe sind und in einer Menge von 0 bis 2 Gew.-% der Beschichtung vorliegen.
10. Tablette für pharmazeutische Zwecke, Nahrungsmittelzwecke sowie für Konditorwaren, die auf ihrer gesamten Außenfläche mit einem Befilmgemisch nach einem der vorangegangenen Ansprüche überzogen ist.
- 40 11. Verfahren zur Herstellung einer Tablette für pharmazeutische Zwecke, Nahrungsmittelzwecke sowie für Konditorwaren nach Anspruch 10, das die wässrige Sprühbeschichtung der gesamten Außenfläche einer Tablette mit dem Befilmgemisch nach einem der Ansprüche 1 bis 8 zur Bildung einer Beschichtung umfaßt.
- 45 12. Verfahren nach Anspruch 11, das das Aufbringen des wäßrigen Befilmgemisches auf unbeschichtete Tabletten durch Versprühen in einer sich langsam drehenden Prallblechwanne in einer Kammer umfaßt, die mit einer Einrichtung zur Messung und Steuerung sowohl der Eintrittsströmungsgeschwindigkeit als auch der Austrittsströmungsgeschwindigkeit der Luft sowie der Temperatur ausgestattet ist, wobei die Eintritts- und Austrittsgeschwindigkeit der Luft und die Temperatur ausreichend hoch sein müssen, um eine rasche Verdampfung des Wassers sowie eine gleichmäßige Beschichtung der unbeschichteten Tabletten zu gewährleisten, ohne daß sich diese zersetzen und/oder zerfallen.

Revendications

- 55 1. Une composition de revêtement comestible formant un film constitué de poudres sèches utilisable dans les comprimés pharmaceutiques alimentaires et de confiserie, comprenant un mélange sec obtenu par mélange à sec des ingrédients incluant des particules pulvérulentes de maltodextrine comestible non

toxique formant un film, de plastifiant et d'agent limitant le caractère poisseux, le plastifiant représentant entre 3,5% et 15% du poids de la composition de revêtement et l'agent limitant le caractère poisseux représentant entre 2% et 20% en poids de la composition de revêtement.

- 5 2. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 1, dans laquelle le plastifiant est du polyéthylèneglycol 400, du sirop de glucose hydrogéné, du polyéthylèneglycol 3350, du polyéthylèneglycol 8000, du triacétine, du citrate d'acétyl-triéthyle, de la glycérine ou une combinaison de ces composés.
- 10 3. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 1 ou 2, dans laquelle ledit agent limitant le caractère poisseux est un dérivé d'amidon modifié, une gomme cristalline, du polyéthylèneglycol 3350 ou du polyéthylèneglycol 8000.
- 15 4. La composition de revêtement comestible formant un film constituée de poudres sèches selon l'une quelconque des revendications 1 à 3, incluant un agent secondaire formant un film qui représente entre 3% et 15% en poids de la composition de revêtement.
- 20 5. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 4, dans laquelle l'agent secondaire formant un film est de l'alginate de propylèneglycol.
- 25 6. La composition de revêtement comestible formant un film constituée de poudres sèches selon l'une quelconque des revendications 1 à 5, comprenant des agents colorants représentant de 0% à 20% en poids de la teneur en composés solides de la composition de revêtement.
- 30 7. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 6, dans laquelle lesdits agents colorants sont le dioxyde de titane, les pigments FD&C ou les pigments D&C.
- 35 8. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 7, dans laquelle le dioxyde de titane représente de 0% à 10% en poids du revêtement.
9. La composition de revêtement comestible formant un film constituée de poudres sèches selon la revendication 6, dans laquelle lesdits ingrédients colorants sont des colorants solubles qui représentent 0% à 2% en poids du revêtement.
- 35 10. Un comprimé pharmaceutique, de confiserie ou alimentaire revêtu sous toutes ses faces externes avec la composition de revêtement selon l'une quelconque des revendications précédentes.
- 40 11. Un procédé de préparation d'un comprimé pharmaceutique de confiserie ou alimentaire selon la revendication 10, comprenant le revêtement par pulvérisation aqueuse de la composition de revêtement selon l'une quelconque des revendications 1 à 8 sur toutes les surfaces externes d'un comprimé pour former un revêtement.
- 45 12. Un procédé selon la revendication 11, qui comprend la pulvérisation d'une composition de revêtement aqueuse sur des comprimés non-revêtu dans un récipient à chicanes tournant lentement, situé dans une chambre qui est équipée pour mesurer et contrôler les températures et les taux d'écoulement d'air à l'entrée et à la sortie, les températures et les taux d'écoulement d'air à l'entrée et à la sortie étant suffisants pour assurer une évaporation rapide de l'eau et pour obtenir un revêtement uniforme sur les comprimés non-revêtu sans provoquer leur décomposition et/ou leur désintégration physique.

50

55